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DATE: September 3, 2004

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TO: Lyle Alexander **Fax: 703-872-9306**

REGARDING:
IL-10691

NUMBER OF PAGES TO FOLLOW: 22

Lyle,

Here is the Brief on Appeal that you are missing.

Thank you very much,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: IL-10691

Applicant: Peter J. Nunes et al

Group Art Unit: 1743

Serial No.: 09/834,138

Examiner: Lyle Alexander

Filed: April 12, 2001

For: Solid Phase Microextraction Field Kit

RECEIPT IS HEREBY ACKNOWLEDGED OF THE FOLLOWING:

1) Transmittal of Brief on Appeal (2 pages) (in triplicate)
2) Brief on Appeal (12 pages) (in triplicate)
3) Appendix A (Claims on Appeal) (6 pages) (in triplicate)
4) Express Mail Certificate of Mailing
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Attorney: JST/tw

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Date Mailed: 7/12/2004

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants :	Peter J. Nunes et al	Appeal No. :	
Serial No. :	09/834,138	Docket No. :	IL-10691
Filed :	April 12, 2001	Art Unit :	1743
For:	Solid Phase Microextraction Field Kit	Examiner :	Lyle Alexander

Commissioner for Patents
Alexandria, VA 22313-1450

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Date of Deposit 7/12/2004

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1. Transmittal of Brief on Appeal (2 pages) (in triplicate)
2. Brief of Appeal (12 pages) (in triplicate)
3. Appendix A (Claims on Appeal) (6 pages) (in triplicate)
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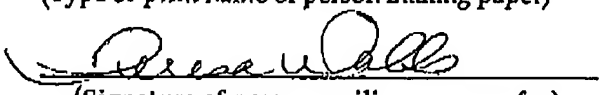

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants :	Peter J. Nunes et al	Docket No. :	IL-10691
Serial No. :	09/834,138	Art Unit :	1743
Filed :	April 12, 2001	Examiner :	Lyle Alexander
Title :	Solid Phase Microextraction Field Kit		

TRANSMITTAL OF BRIEF ON APPEAL (PATENT APPLICATION - 37 CFR 192)

Transmitted herewith in triplicate is the BRIEF ON APPEAL in this application with respect to the Notice of Appeal filed on Feb. 11, 2004 .

The item(s) checked below are appropriate:

1. STATUS OF APPLICANT
   This application is on behalf of
   - ☐ other than a small entity.
   - ■ a small entity.
     A verified statement
     - ☐ is attached
     - ■ already filed.

2. FEE FOR FILING APPEAL BRIEF
   Pursuant to 37 CFR 1.17(e) the fee for filing the Appeal Brief is:

■	small entity	$165.00
☐	other than a small entity	$330.00
	Appeal Brief fee due	$165.00

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3. EXTENSION OF TIME

☐ Applicant petitions for an extension of time under 37 CFR 1.136

Calculation of extension fee (37 CFR 1.17(a)-(d)):

	Total months requested	Fee for other than small entity	Fee for small entity
☐	one month	$110.00	$55.00
☐	two month	$420.00	$210.00
■	three month	$950.00	$475.00
☐	four month	$1480.00	$740.00
☐	five month	$2010.00	$1005.00
		Fee	**$475.00**

4. FEE PAYMENT

■ Charge Account No. 12-0695 in the amount of $ 640.00 .

■ **Charge Account No. 12-0695 for any additional extension and/or fee required or credit for any excess fee paid.**

James S. Tak
Agent for Applicant(s)
Reg. No. 46,367
Tel. No. (925) 422-7274

Date: 7-12-04

PATENT

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Teresa Walls

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants :	Peter J. Nunes et al	Docket No. :	IL-10691
Serial No. :	09/834,138	Art Unit :	1743
Filed :	April 12, 2001	Examiner :	Lyle Alexander
For :	SOLID PHASE MICROEXTRACTION FIELD KIT		

BRIEF ON APPEAL

Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the decision dated August 11, 2003 of the Examiner finally rejecting Claims 1-19. Appellants respectfully request that this Brief be fully considered by the Board and that the Examiner's rejection of the claims be reversed for the reasons stated herein.

I. Real Parties in Interest

The real parties in interest are the Regents of the University of California and the United States of America as represented by the United States Department of Energy.

II. Related Appeals and Interferences

Appellants know of no other appeals and interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of the Claims

Claims 1-19 are pending in this application. Of these, claims 1, 11, 13, 15, and 16 are independent. Claims 1-19 stand finally rejected as obvious.

All pending claims are appealed.

A complete copy of the claims involved in the appeal (as amended during the course of this application) is presented in Appendix A.

IV. Status of Amendments

All amendments have been entered. No amendment under 37 CFR 1.116 has been filed.

V. Summary of the Invention

The invention is set forth in the claims, with certain specific embodiments described in the specification. Generally speaking, and without prejudice to the scope of the claims, the invention relates to SPME sample collection. More particularly, the invention relates to a field-deployable SPME kit having all necessary equipment for performing SPME collection, isolation, and concentration, and including a plurality of hermetically sealed transport tubes each securely retaining and transporting a SPME fiber syringe assembly. The transport tubes are all carried within a common casing, with the transport tubes functioning to prevent cross-contamination between SPME fiber syringe assemblies which may be possible due to external contamination of any one of the SPME fiber syringe assemblies.

VI. Issues Presented For Appeal

The following ultimate issue is presented for appeal: Whether claims 1-19 would have been obvious under 35 U.S.C. §103(a) over "Optimization of the SPME device design for field applications" by Pawliszyn et al. (hereinafter "Pawliszyn") or U.S. Pat. No. 5,693,228 to Koehler et al. (hereinafter "Koehler") in view of U.S. Pat. No. 5,672,883 to Reich (hereinafter "Reich") and further in view of U.S. Pat. No. 4,195,059 to Whitcher et al. (hereinafter "Whitcher") or U.S. Pat. No. 4,303,610 to Sardisco et al. (herinafter "Sardisco")?

VII. Grouping of Claims

Claims 1, 3, 5-8, 10-13, 17 and 19 stand or fall together. Claims 2, 9, and 16 stand or fall together. And claims 4, 14, 15, and 18 stand or fall together. Each of these three groups of claims differ in scope, as described in detail below.

VIII. Arguments

A. Appellants' claims 1-19 are not obvious over Pawliszyn or Koehler in view of Reich, and further in view of Whitcher or Sardisco

Claims 1-19 are rejected under 35 U.S.C. §103(a) as obvious over Pawliszyn or Koehler in view of Reich, and further in view of Whitcher or Sardisco. In support of those rejections, the Examiner stated that Pawliszyn or Koehler teaches SPME fibers within syringe housings and septums, Reich teaches means to protect a syringe assembly during transport, and that it would have been within the skill in the art to modify Pawliszyn or Koehler in view of Reich *"to provide a protective container having an interconnecting top and bottom portion to gain the advantages of preventing premature discharge of the syringe's contents and providing easy/safe disposal of contaminated syringes."* Furthermore, the Examiner also stated that it would have been within the skill in the art to *"bring together all of the essentials in the form of a kit to gain the above advantages,"* such as *"supplying all of the necessaries to perform the test and obviate the problem of trying to assemble the*

components in a hasty fashion possibly missing essential elements. Kits are also advantageous because they are commercially expedient."

A1. <u>No suggestion or motivation exists in the art for combining or modifying the Pawliszyn or Koehler references with the Reich reference</u>

Appellants respectfully submit that the 103(a) rejection of the claims is inappropriate for want of prima facie support of obviousness. This is in view of MPEP § 2142 which states that to establish a *prima facie* case of obviousness, *"there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings."* Furthermore, the teaching or suggestion to make the claimed combination must be found in the prior art, and not based on applicant's disclosure, as stated in *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed Cir. 1991).

In Pawliszyn, various configurations of field portable SPME samplers are disclosed for the purpose of minimizing sample losses from the SPME fiber and of fiber contamination during transport and storage. For example, a silicon rubber septum is provided in one embodiment to seal the tip of a needle where the SPME fiber is retracted during storage. In another embodiment, a two-leaf closure is configured to be opened and closed by adjusting a finger-tight nut, with the needle of the SPME sampler sealed inside the two halves of the closure.

In a third embodiment, a Teflon cap is provided to cover and seal the SPME fiber during transport and storage. And in a fourth embodiment, a valve is provided to seal a retracted SPME fiber inside the barrel portion of the SPME syringe assembly. In all four examples, only the SPME fiber is sealed and protected from exposure, and not the entire SPME fiber syringe assembly. And Reich discloses a combination radiological pig and sharps container to provide radiation shielding of a common syringe assembly containing radiological material.

There is no teaching, suggestion, or motivation, however, in Pawliszyn, Koehler, or Reich to seal and protect a SPME fiber syringe assembly using a sealed transport tube, as required in independent claims 1, 11, 13, 15, and 16. Appellants submit the SPME fiber syringe assemblies, i.e. SPME field samplers, described in Pawliszyn or Koehler are structurally and functionally distinct from the common "syringe assembly" described in Reich. When radiological material is contained in the syringe assembly of Reich, the common syringe assembly has no capability, built-in or otherwise, for sealing and/or radiation shielding the radiological material. The combination radiological pig and sharps container of the Reich patent is therefore utilized to address this specific problem by providing *"some degree of radiation shielding,"* (column 1, lines 48-51) as well as protection against *"the risk of injury posed by the sharp hypodermic needles"* (column 1, lines 51-58).

In contrast, and as correctly noted by the Examiner, SPME field syringe assemblies such as those described in Pawliszyn or Koehler are already provided

with sealing caps or septums, built-in or otherwise, at or near the tip of the active SPME fiber, for sealing the fiber when retracted for storage or transport. As mentioned in Pawliszyn, this is because *"The most important requirement for a reliable field sampler is the minimization of sample losses from the SPME fiber and of fiber contamination during transport and storage."* Thus, whereas the common syringe assemblies in Reich require a separate container to ensure against radiation leakage and contamination, SPME collector/field samplers are already provided with means for fiber sealing and sample protection. Consequently, there is no teaching or suggestion to combine either Pawliszyn or Kochler with Reich to further seal and store an already sealed SPME syringe assembly in a separate transport tube. Nor is there any motivation taught or suggested to do so.

A2. No suggestion or motivation exists in the art for providing a plurality of hermetically sealed transport tubes for individually containing SPME fiber syringe assemblies in a common casing

Also in support of his 103 based rejections of claims 1-19, the Examiner stated the art is silent to the assembly of a plurality of SPME fiber syringe assemblies in a kit, but that according to St. Regis Paper Co. v. Bemins Co., Inc, *"duplication of parts has no significance unless a new and unexpected result is achieved. It is advantageous to duplicated parts in a test kit so that multiple tests may be performed from the same packaging which avoids waste and makes the testing more economical."*

Contrary to the Examiner's view, however, duplication of the transport containers of the present invention is not simply to allow the conduction of multiple tests for economy and efficiency reasons. The plurality of hermetically sealed transport tubes are all carried within a common casing, and function to prevent cross-contamination between SPME fiber syringe assemblies which may be caused by exterior contamination of any one of the syringe assemblies. This is an important goal of the present invention for which there is no teaching or suggestion in any of the cited references. While the prior art teaches sealably storing SPME fibers within syringe housings and septums to prevent contamination of the fiber, it does not address the possible contamination of the SPME syringe housing itself during sampling, and the possible communication of such contaminants to other syringe assemblies and fibers. It is appreciated that the mere fact that references can be combined or modified does not render the resultant combinations obvious unless the prior art also suggests the desirability of the combination. Clearly, there is no such suggestion or motivation in the cited references.

A3. No suggestion or motivation exists in the art for further combining or modifying the Pawliszyn, Koehler, and Reich references with the Whitcher or Sardisco references

The Examiner also stated that Whitcher and Sardisco *"teach test kits supplying all of the necessary items as well as instructions for use in a carrying case.*

The advantages of such a test kit is they supply all of the necessaries to perform the test and obviate the problem of trying to assemble the components in a hasty fashion possibly missing essential elements. Kits are also advantageous because they are commercially expedient." On this point, the Examiner's statements seem to suggest that any type of kit, which supplies all of the necessary items as well as instructions for use in a carrying case, would be obvious in light of Whitcher or Sardisco, irrespective of the particular functionalities provided by the kit's component parts.

Contrary to the Examiner's suggestion, MPEP §2143.03 requires an examination of all the claim limitations in a claim. In the present invention, the claims specify the particular structures and operations of each of the tools provided in the kit, for performing SPME sample collection, and providing safe transport of a SPME collection/sampling device from the field. For example, and as previously discussed, the kit of the present invention includes a plurality of transport tubes for the specific purpose of safely retaining a SPME fiber syringe assembly during transport, and preventing cross-contamination with another SPME fiber syringe assembly retained in another transport tube. In contrast, Sardisco discloses a test kit for field analysis of plant tissue magnesium and calcium, and Whitcher discloses a chemical test kit for testing the condition of water. Both the Whitcher and Sardisco references represent non-analogous art which do not address the same issues and operational concerns/parameters presented in the particular field of the present invention, and therefore do not

provide, teach, or suggest the use of the same or similar kit components and equipment.

A4. Claims 2, 9 and 16 are not obvious over Pawliszn or Koehler in view of Reich, and in further view of Whitcher or Sardisco and each separately patentable

In addition to the aforementioned arguments of non-obviousness, it is submitted that claims 2, 9 and 16 are separately patentable as being non-obvious over Pawliszn or Koehler in view of Reich, and in further view of Whitcher or Sardisco. Claim 2 recites the additional limitation of a means for allowing sampling of an environment within said transport tubes to determine contamination of the retained SPME fiber syringe assembly. Claims 9 and 16 contain similar language (i.e. a "septum" in claim 9 and a "seal" in claim 16). MPEP Section 2142 states in part that for a prima facie case of obviousness *"the prior art reference (or references when combined) must teach or suggest all the claim limitations."* While the Examiner is correct in stating that, *"the cited art teaches SPME fibers within syringe housings and septums,"* there is no teaching or suggestion to incorporate a septum with the transport container. Moreover, the prior art does not teach or suggest providing a pierceable septum or seal for sampling the inner volume within such supplemental transport tube/container to detect if external contamination of the SPME sampler itself has occurred. As previously discussed, the present invention enables the prevention of cross-

contamination, and the septum is used to check against such external contamination of the SPME fiber syringe assembly. In this manner, the function of the septum or seal in the present invention is fundamentally different from that described in the prior art.

A5. Claims 4, 14, 15, and 18 are not obvious over Pawliszn or Koehler in view of Reich, and in further view of Whitcher or Sardisco and each separately patentable

Additionally, Appellants respectfully submit that claims 4, 14, 15, and 18 are separately patentable as being non-obvious over Pawliszn or Koehler in view of Reich, and in further view of Whitcher or Sardisco. These claims include the additional limitation of a fiber protective cap extraction tool for removing the protective cap from the fiber and reinstalling the protective cap on the fiber. As mentioned above, MPEP Section 2142 states in part that for a prima facie case of obviousness *"the prior art reference (or references when combined) must teach or suggest all the claim limitations."*

CONCLUSION

For the aforementioned reasons, Appellants respectfully submit that claims 1-19 distinguish patentably over Pawliszyn or Koehler in view of Reich and Whitcher or Sardisco, and the 103(a) rejections of claims 1-19 are therefore inappropriate and should be reversed.

Respectfully submitted,

Dated: 7-12-04 By:

James S. Tak
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